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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/311,720      | 05/14/1999  | GREGORY M. GLENN     | PM254809            | 1614             |

7590 12/18/2003

MORGAN & LEWIS & BOCKIUS L.L.P.  
1111 PENNSYLVANIA AVENUE N.W.  
WASHINGTON, DC 20004

EXAMINER

WOITACH, JOSEPH T

|          |              |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1632

DATE MAILED: 12/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/311,720

Applicant(s)

GLENN ET AL.

Examiner

Joseph T. Weitach

Art Unit

1632

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 14 November 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:


Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 1-31, 35, 36, 39-41, 44-46, 55-58, 72 and 75-127.

Claim(s) withdrawn from consideration: 32-34, 37, 38, 42, 43, 47-54, 59-71, 73, 74.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
10. ☒ Other: See Continuation Sheet

  
DEBORAH J. REYNOLDS  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

Continuation of 2. NOTE: The claims are not commensurate in scope with the elements set forth in the basis of the rejection as they are directed to administration to mammals, the use of sequestrin sequences, specific promoters, and specific expression levels affected. Further, the term 'antigenic-specific' immune response raises new issues under 112 first and second paragraph regarding the metes and bounds of the claim and enablement for the full breadth of the claim. Additionally, the new limitation of the 'adjuvant is bacterial DNA' was not specifically searched nor considered regarding prior art or breadth of enablement. Newly added claims include the use of specific agents not previously searched nor considered.

Continuation of 5. does NOT place the application in condition for allowance because: As indicated above in section 2 above, the proposed amendments raise new issues requiring further consideration and a new search. Applicants' arguments that the claims are commensurate in scope indicated in the basis of the rejections are not persuasive because review of the final office indicates that the proposed claims are not commensurate in scope. Further, the claim as presented does not provide a generic claim that was subject to restriction requirement. A bacterial DNA as an adjuvant was not specifically set forth in the restriction requirement nor the specification as a species/genus specifically contemplated. Importantly, a CpG sequence does not represent a species of bacterial DNA. Moreover, DNA containing CpG is the adjuvant itself and does not serve to 'encode' an adjuvant as required in step (a) of claims 1 and 80.